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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,342	08/01/2001	Shi-Lung Lin	13761-7024	4134

7590 10/29/2004

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EXAMINER

SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/920,342

Applicant(s)

LIN ET AL.

Examiner

J. D. Schultz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-31, 33, 37 and 46-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32, 34-36 and 38-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8-16-2004</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed August 16, 2004 has been considered. Rejections and/or objections not reiterated from the previous office action mailed May 12, 2004 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on August 16, 2004 was filed before the mailing date of the final Official action enclosed herewith. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner, and an initialed copy is enclosed herewith.

### ***Response to Claim Rejections - 35 USC § 102***

Claims 32, 34-36, and 38-45 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Bennett et al. US Patent 6,066,500, for the same reasons as recited in the rejection mailed May 12, 2004.

Applicants have traversed the instant rejection by asserting that Bennett fails to teach providing a composition comprising an mRNA-CDNA hybrid capable of inhibiting the

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expression of a target gene in a substrate. This argument is based on the assertion that in Bennett, the antisense oligonucleotides are single stranded, whereas the mRNA- CDNA hybrid of the present invention is double stranded.

This is not considered convincing. While the antisense (DNA) oligos of Bennett are single stranded, they become double stranded upon hybridization to their mRNA target. At this point, both method steps have been met, because a DNA/RNA hybrid has been provided and contacted with the substrate (i.e. cell). Therefore, despite the fact that the starting precursors are different from those set forth in applicant's arguments, the final result of Bennett teaches all claim limitations.

Applicants argue further that Bennett cannot make instant claim 32 obvious. However, it is pointed out that the claims are rejected under 35 U.S.C. § 102, not 35 U.S.C. § 103(a). While applicant's argue that Bennett has no teaching or suggestion whatsoever of providing a composition comprising an mRNA-cDNA hybrid, applicant's are directed to the following passage from the "Detailed Description of the Invention" from Bennett:

"This is accomplished by providing antisense compounds which specifically hybridize with one or more nucleic acids encoding Beta catenin. ...The specific hybridization of an oligomeric compound with its target nucleic acid interferes with the normal function of the nucleic acid.

Since Bennett teaches that the antisense can be DNA oligos which are complementary, i.e. cDNA, applicant's assertion that Bennett has no teaching or suggestion whatsoever of providing a composition comprising an mRNA-cDNA hybrid is simply in error.

Applicants argue that the present invention of claim 32 is drawn to RNAi. Claim 32, the independent claim that applicant's arguments focus on, recites:

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A method for inhibiting the expression of a target gene in a substrate that expresses the targeted gene, comprising the steps of: a) providing a composition comprising an mRNA-CDNA hybrid capable of inhibiting the expression of said targeted gene in said substrate; and b) contacting said substrate with said composition under conditions such that the expression of said gene in said substrate is inhibited.

However, the claim language does not exclude the more traditional methods of using antisense molecules as taught by Bennett, because Bennett teaches all the method steps and compositions. Bennett provides a hybrid mRNA-cDNA (albeit following antisense administration) that is inherently contacted with the substrate (i.e. cell) wherein the expression of the gene in the cell is inhibited. For this reason, the rejections of claim 32 under 35 U.S.C. §§ 102(e) and 102(a) are maintained.

Applicants assert that the alleged obviation of claim 32 by way of argument serves to free all dependent claims from the instant rejection. However, since applicant's arguments are not considered convincing, the rejection is also maintained against all dependent claims as well.

### ***Conclusion***

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

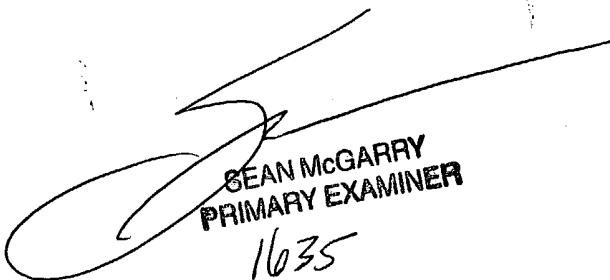
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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JD Schultz, PhD

  
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PRIMARY EXAMINER  
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